

Declaration of Conformity for class I devices

According to MDR 2017/745, Annex IV

Date (yyyy.mm.dd)	Change Description	Author
2023.12.12	Corrected Declaration of Conformity- removed component level stock codes and EU Authorized Rep SRN	Susan Cwiertnia
2024.05.28	Added correct SRN numbers for Manufacturer and EU Authorized Rep, and removed "Moduform" from trade name	Matthew Kosh

Manufacturer

Name: **Bodypoint, Inc.**

Address: 558 1st Ave S, Suite 300, Seattle, WA 98104 USA

SRN: US-MF-000042021

Authorised representative

Name: **Bodypoint Europe, B.V.**

Address: Kerkstraat 29, 7396PG Terwolde, Netherlands

SRN: NL-AR-000017282

We, the manufacturer, declare and ensure with sole responsibility that the below mentioned Medical Device(s) meet(s) the provisions of the Medical Device Regulation 2017/745/EU (MDR) which apply to them. The device(s) covered by the present declaration are in conformity with the MDR 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity (Note: The relevant regulations should be listed).

<u>Product and trade name</u>	<u>Product Code(s)</u> <i>(optional if Basic UDI-DI allows unambiguous identification and traceability of the device)</i>	<u>Basic UDI-DI</u>
Dynamic Arm Support	AS200L	8411801GMN0010FM
	AS200R	
	AS201L	
	AS201R	
	AS001	

Photograph:



Intended purpose of the device:

The Dynamic Arm Support's intended purpose is to support the complete arm with a neutral shoulder position when seated in the wheelchair. Its dynamic inward & outward function allows for movements for functional purposes whilst the hand is support in a neutral position and the forearm movement is limited. The special hand block accommodates for flexion and extension of the hand and absorbs muscles spasms, with the aim to reduce contractions and prevent shoulder subluxation.

Risk class and applicable rule in acc. with Annex VIII: Class I; applicable rule: 1

Common Specifications used: Conforms with EN12183: 2022, EN12184: 2022, ISO16840-10:2021, ISO 10993-5:2009, REACH compliance

Additional information: None

Handwritten signature of Matthew Kosh in blue ink.

Signature

Seattle, WA 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.